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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,167	08/29/2002	Werner Mederski	MERCK 2032A	9724

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 01/29/2004

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,167

Applicant(s)

MEDERSKI ET AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7. 6) ☐ Other:

DETAILED ACTION

Applicant's preliminary amendment of 05-22-02 is acknowledged, and entered. Claims 1-9 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. **Lack of Written Description:** Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 3 recites step (a) which calls for "functional derivatives". There is no description of what these are. On page 18, the specification only describes "functional derivatives" as "functional derivatives depending on the protective group used is known in the present literature...". Even though the protective group is known in the art, it does not mean a 'functional derivative' of formula I is described. For one thing, one does not know the location of the protective group on formula I that would constitute a 'functional derivative'. Secondly,

the hydrolyzed product might not be the intended compound of the claimed formula I. Thus, the limitation of “functional derivatives” lacks a written description.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-6, 8, and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a. Claims 1, 2, and 4-6 appear to be a compound claims. However, they are also recite the phrase “and their pharmaceutically tolerable salts...”, which suggests a mixture, and thus, a composition. Therefore, it is unclear if these are compound or composition claims. Applicant is advised to replace the word “Compounds” with “A compound”; also replace the phrase “and their pharmaceutically tolerable salts...” with “or a pharmaceutically tolerable salt thereof...”

b. Claim 1 recites the limitation of “solid phase”. However, the specification indicates that this is not a permanent feature of the final product. Thus, it is unclear what the final structure is if the “solid phase” gets removed from the compound.

c. Claim 3, step (c) recites the limitation of “a radical.....is converted into another radical...”, which is not clear as to what is converted into what. That is, it is not clear if

any of those variables is converted to each other, or to itself. If each of those variables is converted from one functional group to another, then it is not clear what functional group is converted into what.

d. Claim 3, step (c) also recites the phrase “for example” which renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

e. Claims 4-6 appear to have the same scope with claim 1, since the intended uses in those claims do not result in a structural change in formula I. Thus, those claims appear as substantial duplicates of claim 1.

f. **Use Claims:** Claims 8 and 9 provide for the use of compounds of formula I, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 8 and 9 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claim 1, 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Houghten et. al.** (WO 98/11438, or US 5,783,577). On pages 9-12 of WO'438 (or columns 5 and 6 of US'577), Houghten et. al. discloses a subgenus of formula II (or, N-styryl derivatives of quinazolinones) in which its R^1 represents $-\text{CH}(\text{CH}_2\text{-cyclohexyl})-$, and its Y can be an amino resin. Said subgenus generically reads on the claimed formula (I) with the following substituents:

- i. $n = 0$; $m = 2$; $-\text{NR}^2\text{R}^3$ is an amino resin;
- ii. R and R^1 can be hydrogen, alkyl, halogen, etc.;
- iii. Y represents an alkenyl group of 2 carbon atoms;
- iv. R^4 is Ar or phenyl (unsubstituted or substituted);

The reference differs from the claims by not disclosing a species of N-styryl quinazolinone, and not relating its formula II to the activity of a glycoprotein IbIX antagonist. However, the disclosed formula II lists substituents that are specific enough to guide one skilled in the art to select quinazolinone compounds with substituents as recited in the instant claims. Furthermore, Houghten et. al. acknowledge several pharmacological uses on page 1 of WO'438 (or column 1 of US'577) (e.g., antimalarial, hypnotic, sedative, analgesic, anticonvulsant, anti-tussive, anti-inflammatory property, etc.). Thus, one of the ordinary skill in the art would have been motivated to select compounds of the claimed formula (I) because one would have expected those compounds to have a pharmacological property acknowledged by Houghten et. al.

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Therefore, it would have been obvious for one skilled in the art to make the compounds and their pharmaceutical compositions as claimed herein in view of Houghten et. al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9 am - 5:30 pm) starting from January 12th, 2004.

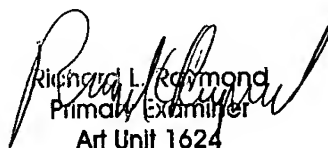
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



T. Truong

January 23, 2004



Richard L. Raymond
Primary Examiner
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